

mortality data. What is surprising is that Dr. Whitehouse presents this quote to demonstrate that the people of Libby were exposed to a more toxic asbestos situation than the insulators.

It is not scientifically valid to interpret the age at death data the way Dr. Whitehouse does. In paragraph 32, page 21, 2008 Whitehouse expert report, he states that "it is apparent that exposure to Libby asbestos is considerably more toxic to humans than was the predominantly chrysotile exposure of the insulation workers." In paragraph 35 on the same subject of the purported differential toxicity of the Libby vermiculite, Dr. Whitehouse states that "an important aspect of Libby area exposures is that residents had a 24-hour exposure, with no respite away from exposure to clear out airways. This appears to be generally different from exposures reported elsewhere". (Whitehouse 2008 report, page 26) His argument is scientifically inconsistent. How could exposure to Libby asbestos be more toxic to human beings than the exposure experienced by the insulator cohort, given that the insulators died on average more than 10 years earlier than the CARD mortality data? This seems especially inconsistent when one considers Whitehouse's claim that one of the factors that made Libby exposure more toxic was that it was 24/7.

#### D. 'Death Rate' in the CARD mortality data

In paragraph 32, page 19 of his expert report, Dr. Whitehouse states that "the 62% death rate from asbestos disease appears to be the highest reported for any cohort in the United States." This statement is logically impossible, because as noted above, the CARD mortality data contains only dead subjects. One computes a mortality (death) rate by dividing the number of people who die by the total number of people alive in any group of interest. I believe what Dr. Whitehouse is trying to say is that the proportional mortality from asbestos disease in this

haphazardly selected cohort is 62%. Given the lack of meaningful selection criteria, interpretation of this proportion is not possible. As noted above, there is no scientifically valid way to compare such a proportion to any other group of people.

E. ATSDR mortality study and community exposure to Libby Vermiculite

Let us now turn to the updated mortality study of deaths occurring in Libby, Montana from 1979 to 1998, conducted by ATSDR and reported in August of 2002. As noted above, this study is a classic SMR-type study. That means that information on all deaths that occur in a defined group of people, in this case all residents of Libby and the surrounding area of central Lincoln County, are located under a well-defined protocol for ascertaining deaths, cause of death, location of death. Information on which decedents were employed in the Libby facilities was collected from two separate sources and then combined. The first was an employment database consisting of historical records on over 1800 employees from the vermiculite mine and milling facility in Libby. The second source was information obtained during ATSDR's medical screening program conducted in Libby during the summers of 2000 and 2001. In all, data on over 1950 previous employees of W.R. Grace were compiled through these sources. The mortality data was compared to the W.R. Grace database to determine if deceased subjects had ever been employed at the facility. The W.R. Grace database was also used to determine the length of employment for any decedents that were previous workers. Using this systematically collected information about deaths occurring in the Libby area, the ATSDR concluded (in 2002) that "most of the excess and respiratory mortality can likely be attributed to occupational exposures since several decedents (12%, 64/542) were former workers at the mining and milling facility. Asbestosis and mesothelioma mortality were found almost exclusively in former workers.

Increases in lung cancer mortality also could be explained by occupational association with the mine and milling facility.” (ATSDR 2002, page 10).

Table 8 of the ATSDR study directly addresses Dr. Whitehouse's claims of excess respiratory disease mortality in non-occupationally exposed residents of Libby, Montana. The SMR, using either Montana or the United States as a comparison from combined respiratory disease causes, shows no overall excess of mortality from respiratory disease in non-occupationally exposed residents of central Lincoln County, Montana. This epidemiologically valid SMR analysis presents quite different results than Dr. Whitehouse claims the CARD mortality data analysis shows. Compared to Dr. Whitehouse's study, the ATSDR mortality study uses a valid selection process for cases and a valid application of the SMR approach. As a result, the ATSDR analysis produces information on which a scientist can make scientifically valid inferences; Dr. Whitehouse's analysis does not produce information on which a scientist can make scientifically valid inferences.

In his March 19, 2009 deposition, Dr. Whitehouse dismisses the ATSDR Mortality Study as “garbage.” (Whitehouse Deposition, 3/19/09, page 136). Dr. Whitehouse identifies a number of alleged deficiencies with the ATSDR Mortality Study. First, Dr. Whitehouse criticizes the fact that ATSDR relied on death certificates alone and did not review medical charts in conjunction with death certificates. (Whitehouse Deposition, 3/19/09, page 136 – 138). Second, Dr. Whitehouse claims that many asbestosis deaths had been misclassified as COPD deaths. (Whitehouse Deposition, 3/19/09, page 135 – 146). Third, Dr. Whitehouse, in his expert report, claimed that the ATSDR Mortality Study is overly conservative because it only counted primary cause of death and did not consider underlying conditions. (December 2008 Whitehouse Expert

Report, page 39, paragraph 48) Fourth, Dr. Whitehouse, also in his expert report, criticizes the ATSDR Mortality Study for only collecting death certificates for those individuals who were Libby residents at time of death. (December 2008 Whitehouse Expert Report, page 39, paragraph 48) Finally, Dr. Whitehouse describes the ATSDR Mortality Study as based on “crummy data.” (Whitehouse Deposition, 3/19/09, page 139, 141).

With respect to his first criticism - relying on death certificates alone - Dr. Whitehouse himself relied on the ATSDR’s findings with respect to the increased mortality from asbestosis as a result of working for W.R. Grace, specifically, that the worker’s “standardized mortality ratio [was] 65X higher than that of the U.S. reference population” with respect to asbestosis. (Whitehouse Deposition, 3/19/09, page 38 – 39). Moreover, this method of evaluating mortality based on death certificates alone is a well-defined, standardized, and frequently employed method for investigating illnesses suspected of being caused by workplace or environmental exposures, utilized by NIOSH, ATSDR, CDC, and other public health organizations and university-based personnel.

Dr. Whitehouse’s second criticism, that asbestosis deaths were misclassified as COPD deaths, is also misplaced. As Dr. Nicholson noted in his seminal work, the problem of misclassification of death is ameliorated when considering an entire class of diseases, such as all respiratory diseases. (Nicholson et al. Occupational Exposure to Asbestos: Population at Risk and Projected Mortality – 1980-2030. Am J of Ind Med, 1982, p. 290). If a death was misclassified as COPD rather than asbestosis, there would still be an excess in mortality when looking at all respiratory diseases combined. Moreover, if as Whitehouse claims, asbestosis deaths are misclassified as COPD deaths, there should be an excess of COPD deaths. However, when examining the data in Table

8 of the ATSDR Mortality Study, there is not an elevated mortality risk for either COPD or all respiratory causes combined. At his deposition, Dr. Whitehouse acknowledged this fact. (Whitehouse Deposition, 3/19/09, page 139 – 142). The absence of elevated mortality risk in the COPD and all respiratory disease combined listed on Table 8 negates Dr. Whitehouse's criticism that the asbestosis deaths in the community in Libby were misclassified as COPD. Likewise, Table 7 of the ATSDR Mortality Study shows an elevated mortality risk from asbestosis among workers and no elevated risk for COPD compared to the Montana population. This suggests that asbestosis is being correctly identified on death certificates in Libby, and not lumped into COPD as Whitehouse claims.

Dr. Whitehouse's third criticism of the ATSDR Mortality Study correctly notes that the ATSDR only looked at primary cause of death and did not consider underlying conditions. In Table 7 of the 2002 report, the ATSDR notes 12 asbestosis deaths among the 506 total deaths they examined. Based on this data from Table 7, I calculate that 2.4% of all deaths studied by ATSDR were caused by asbestosis. Over approximately the same years encompassed by the ATSDR study, 1979 - 1998, NIOSH has consistently shown that, in the United States as a whole, for every death attributed to asbestosis on a death certificate, there are about two more in which asbestosis is a contributing cause. Even if we multiplied the 2.4% by three to account for asbestosis as an underlying cause, the NIOSH data would suggest that about 7.2% of all deaths involve asbestosis. In order to get to the 40 to 60% of deaths attributable to asbestosis that Whitehouse claims, we would have to make the scientifically indefensible assumption that every one of the 253 deaths from combined respiratory mortality shown in Table 7 would have to involve asbestosis ( $253/506 = 50\%$ ). That we would have to make such an untenable assumption

demonstrates just how unrepresentative Dr. Whitehouse's CARD mortality data is of the general Libby area population.

Dr. Whitehouse's fourth criticism, that the ATSDR only collected death certificates for people who were Libby residents at time of death, simply is not true. On page 2 of the August of 2002 ATSDR Mortality Study, it states "for those Libby residents dying outside of Montana, death certificates were sought from their respective states . . . ." Eleven states were listed in the report.

Finally, Dr. Whitehouse asserts that the ATSDR Mortality Study was based on "crummy data." In his March 2009 deposition, when pressed as to why he thought the data was "crummy," he acknowledged that he had never reviewed the data (Whitehouse Deposition, 3/19/09, pages 143 – 145). This is a surprising admission.

#### F. Asbestosis in the ATSDR mortality cohort compared to CARD mortality data

One can get an idea of how unrepresentative people in the CARD mortality data are by looking at asbestosis in the CARD mortality data compared to the ATSDR mortality data. Referring again to the table (page 22, paragraph 32 of Whitehouse's 2008 report) data is presented showing that asbestosis accounts for 42% of all deaths. In paragraph 42, page 31 of his report, Dr. Whitehouse notes that "65% (117/186) of deceased patients of CARD died of asbestos disease, meaning that asbestos-related disease was at least a significant contributing factor in the death." Further along in that paragraph he notes that "in contrast, a patient diagnosed with asbestos disease from predominantly chrysotile exposure has a much lower likelihood of death." Again, putting aside the obvious inconsistency in the presentation of his data, he claims that at least 42% of deaths are related to asbestosis.

The lack of validity of Dr. Whitehouse's claim that non-occupationally exposed Libby residents have dramatically high mortality from asbestosis becomes even more apparent when we look at the data in Table 8 where there is only one death from asbestosis among 195 total deaths in people who have no occupational exposure. Again, making the invalid assumption that all 195 deaths from respiratory causes involve asbestosis, yields only 38.5% attributed to asbestosis under this extreme and untenable assumption. This data from Table 8 of the ATSDR study further puts Dr. Whitehouse's comments in context. In paragraph 32, page 23 of his 2008 expert report, Dr. Whitehouse states "the most striking observation is that the CARD patient's death rate from asbestosis is about 4X that of the insulators (42% to 11%). This result appears despite the important difference in exposure levels. 63% (50/79) of the CARD patient's were a family or community members with light exposures, whereas insulators had industrial exposures to asbestos which were generally quite extreme." Given that the ATSDR attributes one death to asbestosis among people with no occupational exposure to asbestos, Dr. Whitehouse's "striking observation" is truly striking; however, what's truly striking is just how far removed Dr. Whitehouse's claim is from the systematically and scientifically collected ATSDR mortality. The ATSDR notes in its executive summary, "this comparison of worker records with mortality data demonstrated that the majority (92%, 11/12) of asbestosis decedents... were prior employees at the vermiculite facility."

G. Comparisons of Dr. Whitehouse's CARD data with the results of the 2007 Sullivan Study

In 2007, Dr. Sullivan published a further follow-up to the Amandus occupational mortality study ascertaining deaths through 2001. (Sullivan PA. Vermiculite, Respiratory Disease, and Asbestos Exposure in Libby, Montana: Update of a Cohort Mortality Study. *Env Health Perspect* 115:579-



585 (2007)). In this report, which focuses on the 1672 white male Libby workers identified by company records, Sullivan was able to make exposure specific estimates of risk of respiratory diseases for these occupationally exposed workers. It is noteworthy that 19 of the 22 deaths attributable to asbestosis occurred in those workers with cumulative exposure to asbestos greater than 50 fibers/cc-years. This dose response finding with respect to asbestosis strongly contradicts Dr. Whitehouse's contention that Libby residents with scant environmental exposures have high risks of developing asbestosis. Moreover, it certainly undermines Dr. Whitehouse's contention that individuals whose only exposures were light environmental exposures have risks of asbestosis greater than the very heavily exposed men in the insulators cohort.

It is noteworthy that Sullivan says on page 583 that "SMR observed here for asbestos exposed vermiculite workers are similar to those reported in other studies of asbestos exposed workers." Sullivan's own conclusions further undermine Dr. Whitehouse's contention that the results of asbestos exposure in Libby are unique and unseen elsewhere.

H. Dr. Whitehouse asserts in paragraph 32, page 22 of his 2008 expert report when speaking of the Markowitz study compared to the CARD mortality data that "though the studies differ in minor respects, they are epidemiologically comparable." The Markowitz study is one of a number of reports published on the Selikoff cohort of insulators which was established in 1967 and followed forward in time. The insulator study established a cohort of all members of one union (International Association of Heat and Frost Insulators and Asbestos Workers) whose members had exposure to asbestos as insulators. All union members were invited to enroll; information was collected by questionnaire about personal characteristics and every time a member dies the union notifies the study personnel. This cohort meets the standard of having



information collected in a way that is well-defined by a protocol, systematic, as free from bias as possible and as complete as possible. The Markowitz study attempts to study a subset of the original insulator cohort who were still alive in 1981. As such, the Markowitz study is based on a group of people who were alive and exposed to asbestos who were followed forward in time. The diseases that they developed were carefully ascertained and were turned into incidence rates by dividing the number of people developing each disease by the number originally enrolled. As we have seen the people who are described by the CARD mortality data are haphazardly identified sample of people, not followed under protocol, some of whom were referred from a law firm. The sampling method used to enroll people into the CARD mortality data required that they all be exposed to asbestos and dead. At best, I would describe this study as a group of haphazardly collected deaths. It is simply incorrect to say that the CARD mortality data and information deriving from it are comparable to the carefully constructed and followed insulator cohort. They couldn't be more different.

#### IV. Other Assertions made by Dr. Whitehouse

A. In paragraph 35, page 27, Dr. Whitehouse states in his 2008 expert report that "very few patients had exposures to other asbestos outside the Libby area." In the August 2002 study of environmental cases by the ATSDR mentioned above, the ATSDR notes that that 4/22 patients had been exposed to commercial asbestos from non-vermiculite sources. Almost 1/5 of the ATSDR sample was exposed to other asbestos outside the Libby area. Describing this as "very few" is inaccurate. Further down on page 27, Dr. Whitehouse claims that "all patients in the over 1800 diagnosed above have asbestos disease due to exposure to Libby asbestos with its source in the W.R. Grace and Zonolite company mining and other activities." Considering the above

ATSDR data, it is demonstratively false to claim that all patients who have asbestos disease in Libby developed that disease solely from their exposure to W.R. Grace vermiculite.

B In his 2004 paper, Dr. Whitehouse purports to study asbestos-pleural disease from tremolite exposure, which he claims is associated with a progressive loss of lung function. He begins by choosing 491 patients from his clinical practice. Dr. Whitehouse does not indicate how he selected these 491 patients but does note that they are not among the 1,000 plus individuals who were identified by the ATSDR Screening Study as having pleural abnormalities (Whitehouse, 2004, page 220). (I have subsequently been shown data comparing those screened positive by ATSDR with the 491 people identified in Whitehouse 2004 (Master Cross-Over Spreadsheet compiled by Dr. David Weill). It is clear from this spreadsheet that there is overlap, and that his statement in the published paper is incorrect). Clearly, Dr. Whitehouse did not specify from what population the 491 individuals were selected. From these 491 individuals, he selects 153 individuals whom he states have two or more pulmonary function tests (Whitehouse 2004, page 221). He then states "these subjects are representative of the Libby area population and the practice group of 491 patients" (Whitehouse 2004, page 221). From these 153, it appears that 123 form the basis of the 2004 paper. He does not explicitly tell us how the 153 are decremented to the 123 that make up the study subjects of the 2004 report. There is a statement on page 220 that 30 subjects were removed from the study at some unspecified point for various reasons. (In any case, whenever they were removed, it appears that this was not a true statement as Dr. Whitehouse, at his March 19, 2009 deposition, acknowledged that selection criteria may not have been applied as stated in the paper. Surprisingly, when asked whether he thinks it was important for the paper to reflect what was actually done, he responded "not necessarily").

Dr. Whitehouse, nevertheless, makes the claim in his paper that the 153 individuals “are representative of the Libby area population and the practice group of 491 patients” (Whitehouse 2004, page 221). As discussed above, the claim that a sample or sub-group is representative of a larger population is a meaningful statement in epidemiology. Without establishing the ways in which a sub-group is representative of a larger population, there is no possibility of making a valid extrapolation from the sub-group to the larger population. To say one group is representative of another requires looking at the selection process and comparing the general characteristics of the sub-group to the larger group -- in this case, specific characteristics such as work history and exposure history. In Whitehouse 2004, there are two assertions with respect to representativeness: This group of 153 is representative of the Libby area population, generally, and these 153 people are representative of the 491 people in his clinic.

With respect to the claim that the 153 individuals are representative of the Libby area population, he gives us no supporting information for his claim of representativeness. And in fact, in his March 19, 2009 deposition, Dr. Whitehouse backs away from his claim that these 153/123 individuals are representative of the Libby area population (Whitehouse Deposition, 3/19/2009, page 196). When asked whether it is an issue as to whether the 153/123 are actually representative of the Libby area population, Dr. Whitehouse simply says no (Whitehouse Deposition, 3/19/2009, page 198). Again, this is a rather surprising statement. In the same deposition, Dr. Whitehouse acknowledges that he does not have good criteria for determining whether one group is representative of another (Whitehouse Deposition, 3/19/2009, page 235).

With respect to the claim that the 123 are representative of the 491, examining Whitehouse’s own data of the work history and exposure history of his subjects reveals that this is not true. Dr.

Whitehouse reports that 70% of the 123 people ultimately included in the study were former Grace workers, whereas only 45% of the 491 patients were former Grace workers. Moreover, only 8% of the people in the 123 people in the study were alleged environmentally exposed individuals, whereas 31% of the people in the 491 person patient group were alleged environmentally exposed individuals.

Other data that would enable us to determine whether the 123/153 were in fact representative of the 491 patient group include specific information about the nature of past asbestos exposures, the duration and intensity of exposures, how long they lived in Libby, and the age and gender of the two groups. While Whitehouse (2004) does identify the average age and gender of the 123/153, it provides no similar information on the 491 person patient group. In addition, there is no specific information about their exposures, making it impossible to support the statement about their exposures. Lacking such exposure information makes it impossible to support the statement that the 123/153 are representative of the 491 person patient group.

Furthermore, two or more PFTs are required to enter this study. Because of this requirement, the 123 will likely include people who have more advanced disease than those with one PFT, those in the 491 patient group who were not in the study. At the very least I would have expected Dr. Whitehouse to tell us how the baseline PFT for the 123/153 compared to the single PFT administered to the remaining people in the 491 person patient group. Without this information we cannot determine to what extent the disease severity in the 123 is like the disease severity in the 491.

Dr. Whitehouse provides no supporting information that his study population of 123 is representative of the Libby population. As such neither he nor any other scientist can validly

claim that the findings in these 123 people are representative of the Libby population or for that matter any population other than 123 people themselves.